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RECOGNIZING INDIGENOUS TRADITIONAL KNOWLEDGE WITH MEDICINAL VALUE WITHIN A LEGAL FRAMEWORK: AN OVERVIEW OF THE ISSUES AND CHALLENGES WITH SPECIAL FOCUS ON INDIA

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Abstract: Recognizing traditional knowledge with medical value among Indigenous people is indispensable to sustaining their way of life. However, legal complexities and challenges exist in recognizing the medical value of traditional knowledge, as it is orally transmitted and thus undocumented. While a global solution to such difficulties cannot employ a "one size fits all" approach and invokes multifaceted solutions within national regulatory and policy contexts, India has shown progress in this area. Yet, appropriate guidelines for incorporating the diverse medical knowledge of Indigenous people under a coherent framework must be developed so that Indigenous people can enjoy, and utilize, their rights regarding this knowledge. The objective was to unfold the current situation of traditional medicinal value among Indian Indigenous communities and find ways of recognizing this knowledge within India's intellectual property rights (IPR) legal regime. The present study was based on secondary data sources. A specific literature review was done using the key word "Traditional Knowledge", combined with "Intellectual Property Rights", "Tribes", "Medicinal Plant", "Ethno-medicine", "Folk Lore", "Medical Anthropology", "World Health Organization (WHO)", "Traditional Knowledge Digital Library (TKDL)", World Intellectual Property Organization (WIPO), "Patent Act", "Illness and Sickness" and "India" on PubMed, Google Scholar and other relevant online and offline sources from March 2021 to September 2023. Our findings recommend a multi-tiered approach to documenting traditional medical knowledge, sensitive to regional diversities within India, as a necessary precursor to legal recognition. Therefore, a human rights approach, particularly from the viewpoint of cultural rights, could be a best fit both to recognize the traditional knowledge as a cultural right and to offer the community as the right holder of the knowledge. Hence, appropriate guidelines to that direction should be formulated for incorporating the dispersed traditional medical knowledge of Indigenous people under a coherent framework so that they can enjoy, and utilize, their rights to this knowledge especially in the diverse Indian context.

Keywords: Traditional knowledge, Tribes, Intellectual Property Rights, Medicinal Plant, WIPO, WHO, Act, India

Introduction

Globally, there is broad academic agreement that the Traditional Knowledge (TK) of Indigenous people needs to be protected through a comprehensive framework similar to that of the Intellectual Property Rights (IPR). However, protecting TK is complex. Nations have varied ways of recognizing non-traditional intellectual creations, e.g., creations arising out of TK. Given the importance of TK and its

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value to Indigenous communities, its legal protection will promote the rights of Indigenous communities and eventually offer them benefits arising from the use of their TK. Of the different kinds of Indigenous TK, knowledge of traditional medicine plays a crucial role in healthcare-seeking behavior and primary health needs among Indigenous people. A significant part of the knowledge on traditional medicines has passed through oral tradition and possesses deep-rooted cultural meaning. The recent degradation of knowledge due to changing Indigenous societies encourages us to consider the preservation of knowledge through the application of IPR regimes adapted to national regulatory mechanisms. In this paper, we offer an overview of TK of Indigenous people, its importance, the legal complexities regarding its recognition, and the lack of a general international standard for its protection. We particularly focus on knowledge of traditional medicine among the Indian Indigenous communities, so called "Scheduled Tribes", who possess an enormous amount of knowledge of traditional medicine. However, incorporating traditional medicinal knowledge of Indigenous people in the Indian national Traditional Knowledge Digital Library (TKDL) is complicated by a number of factors, including India's existing regulatory framework. In this context, a bill was proposed in the Indian Parliament entitled "The Protection of Traditional Knowledge Bill, 2022" (Bill no 87 of 2022) with a motto to ensure for the in-situ protection (legal safeguards), preservation, promotion and sustainable development of India's TK including knowledge of traditional medicine of Indian tribes but the problem is remaining same (Tharoor, 2022). The present study aims to unfold the current situation of traditional medicinal value among Indian Indigenous communities and suggest ways of recognizing this knowledge, among others, within human rights framework.

Methodology

Given that the article analyzes legal and regulatory challenges for including traditional knowledge in relation to Indigenous peoples' medicinal knowledge, its objective does not necessarily demand any empirical first-hand data. Instead, as presented in its scope, plenty of literature is available that provides the necessary information for a sound analysis to meet the objective of this article. Therefore, present study was based on secondary data sources. A specific literature review was done using the key word "Traditional Knowledge", combined with "Intellectual Property Rights", "Tribes", "Medicinal Plant", "Ethno-medicine", "Folk Lore", "Medical Anthropology", "World Health Organization (WHO)", "Traditional Knowledge Digital Library (TKDL)", World Intellectual Property Organization (WIPO), "Patent Act", "Illness and Sickness" and "India" on PubMed, Google Scholar and offline sources such as policy documents and published official reports, from March 2021 to September 2023. Literatures related to the overview of the traditional medicinal practices by Indian Indigenous communities were screened

using PRISMA guidelines. In order to minimize the selection bias, the literatures on medicinal traditional medicinal practices of Indian tribal communities was collected from 2000 to 2023.

Indigenous Traditional Knowledge

Conceptualizing TK

TK is a system of knowledge that captures worldviews proven to be authentic through long observation. It does not refer to knowledge that is outdated or old-fashioned as opposed to "modern." Instead, it is a tradition-based creation and a multifaceted concept that includes cultural identity, practical knowledge, oral tradition, spiritual and religious beliefs, and aesthetics (Twarog, 2004). It refers to various elements of informal knowledge generally held by Indigenous and local communities. Such culturally driven norms, practices, and values held by Indigenous peoples shape customary rules informing that their communities act in certain ways while forming a harmonious relationship with the natural environment that surrounds them.TK involves a variety of knowledge developed through traditional practices –practices embedded in the local cultures of Indigenous or traditional communities. These practices generate knowledge that is integrated with society and its value system. It includes wisdom, teaching, customary practices, and particular forms of expression that pass from person to person and from one generation to another. In most cases, such knowledge is expressed through stories, legends, folklore, rituals, songs, and strict customary social practices treated as general customary rules. A community holding knowledge bears a responsibility to carry and transmit it to the next generation, while at the same time they incur the responsibility of ensuring the proper utilization of this knowledge in accordance with their own terms and practices. It is not necessary that knowledge be ancient or static (Gervais, 2005; Long, 2006). Like any other form of knowledge, TK is developed continuously in response to new needs and experiences (Tagle, 2011; Haugen, 2005).

These elements of knowledge are orally transmitted and therefore not found in written form. As such, there is no authoritative definition of TK. Yet, various working definitions encompass TK as a culture-based phenomenon connected to nature, the environment, and ecology. The World Intellectual Property Organization (WIPO) asserts that TK refers to know-how, skills, innovations, practices, teachings, and learnings of Indigenous peoples and local communities, all of which are dynamic, evolving, and intergenerational and which may subsist in codified, oral, or other forms (WIPO, 2013). The World Trade Organization (WTO) also recognized knowledge associated with genetic resources as Indigenous TK. According to Convention on Biological Diversity (CBD) genetic resources contain genetic information of values and have reproducing ability like medicinal plants, which is utilize and conserve by Indigenous peoples and local communities over

the generation ((WIPO, 2013). Among others, the most-cited definition adopted by the Traditional Knowledge Working Group of the Government of the North West Territories (GNWT) of TK is as follows:

knowledge that derives from, or is rooted in the traditional way of life of aboriginal people. Traditional knowledge is the accumulated knowledge and understanding of the human place in relation to the universe. This encompasses spiritual relationship, relationship with the natural environment and the use of natural resources, relationships between people, and is reflected in language, social organization, values, institutions and laws (Legat, 1991)

The characteristics of TK therefore include localness, oral transmission, origin in practical experience, emphasis on the empirical rather than theoretical, repetitiveness, changeability, being widely shared, fragmentary distribution, orientation to practical performance, and holism (Tagle, 2011). To a great extent, such characteristics are related to plants, their properties, and methods for their use, including nutritional or medicinal knowledge, as well as information on other properties of plants and animals, forests and environmental conservation, the properties of minerals and soils, ecosystems, agriculture, and climate change (Tagle, 2011).

Therefore, oral narratives that recount human histories; cosmological observations and modes of reckoning time; symbolic and decorative methods of communication; techniques for planting and harvesting; specialized understandings of local ecosystems; and the manufacture of specialized tools and technologies (e.g., flint knapping, hide tanning, pottery-making, and concocting medicinal remedies) are considered Indigenous TK (Bruchac, 2014). According to the Secretariat of the Convention on Biological Diversity (SCBD), Article 8(j), traditional knowledge is the knowledge, innovations, and practices of Indigenous and local communities around the world. For example, identification of medicinal plants, extraction of the particular parts like leaves, stems or roots and thereafter preparation in the form of medicine by adding others ingredients like honey, pepper, etc and the ways of preserving the medicine for future use, these all are integral to Indigenous peoples' knowledge systems (Haugen, 2005; Cottier and Panizzon, 2004; Kuanpoth, 2009). We see the value of knowledge in the course of its evolvement as uniform and unique. Therefore, we use the term "Traditional Knowledge" and "Indigenous Traditional Knowledge" as "Traditional Knowledge" and specific emphasize to be made on traditional medical knowledge.

Importance of understanding traditional medical knowledge

The World Health Organization (WHO) defines traditional medicine as "the total of the knowledge, skills and practices based on the theories, beliefs and experiences Indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses" (WHO, 2014)

Maintaining such knowledge has become more urgent, given that external expropriation largely results in the deprivation of both ownership rights and the right of benefit-sharing that arises from the utilization of this knowledge. TK has become more uncertain with the development of modern communication, whereby TK is appropriated faster than the bio-resources into which it provides insight. This has led to patent rights claims on products derived from TK, and yet there is a refusal to acknowledge its economic value to and ownership by the communities from which it originates (Oli, 2009). Therefore, the protection and preservation of traditional medicinal knowledge through a legal framework, (e.g., IPR), requires explicit attention to protecting the rights of the Indigenous people and helping traditional medical knowledge remain intact. A protection regime will also help defend the knowledge from threats of theft and abuse.

Knowledge constitutes crucial elements of a holistic identity for a group and, thus, its validity or the value cannot simply be ignored (Haugen, 2005). The identity of these groups of peoples is associated with both natural and human-made livelihoods (Haugen, ibid). Generally, therefore, a particular community holds TK collectively. First, genetic resources cannot be owned; second, it is difficult to properly identify and trace knowledge holders, mostly because such knowledge exists under collective ownership of a community (Gervais, 2005; Tagle, 2011). However, recent developments suggest that TK can be held by an individual, a group, or a community as a whole (Oli, 2009), emphasis has been placed on subjects who belong to the traditional community (generally the Indigenous community) as holders of the knowledge, since they gain such knowledge through continual observation and transmit the knowledge among members of the community.

Indigenous TK, especially concerning plant protection, access to genetic resources, knowledge concerning conservation, and the sustainable use of biological resources, is linked to the conservation of biodiversity and to environmental sustainability. Thus, these cannot be pursued without paying due attention to Indigenous TK or traditional ecological and local knowledge (Burgess, 1999). At present, TK is recognized in the Convention on Biological Diversity (CBD), in the work of the WIPO, as well as in the World Trade Organization - Trade-Related Aspects of Intellectual Property Rights (WTO-TRIPS) Agreement (Bhatti, 2000). The institutions within these instruments also cooperate in protecting TK. In pursuit of its objective, WIPO cooperates with the CBD Secretariat to protect intellectual property in relation to TK. In addition, these instruments also put emphasis on the relevance of other international legal obligations of states, such as obligations arising from human rights treaties, in order to see Indigenous TK protected.

Legal Complexity of Recognizing TK

Due to its nature, such as its being practice-based and orally produced knowledge with no concrete individual ownership, Indigenous TK faces clear challenges in

legal recognition. The legal framework applicable to protecting knowledge and innovation is directed by the IPR regime. The IP regime is designed to protect individual and private intellectual creations as property. The central idea of IPR is to maintain the recognition of invention and to grant ownership rights to authors, as well as to protect the commercial value incurred by that particular authorship. IPR include the identified author(s), identified object or creation, and defined restricted acts (Gervais, 2005). IPR are attached to a market-based phenomenon since they create commercial value (Downes, 1997).

The IPR regime, however, does not generally offer legal protection for any form of 'informal knowledge, such as TK. Therefore, even though Indigenous TK has elements of intellectual knowledge similar to those of the IPR regime, identification of the knowledge itself and its undisputed owners are the primary obstacles to legally protecting it.

TK is considered informal and publicly available knowledge given its roots in the traditional practices of a particular community. This leads to the argument that TK remains within the public domain and the public at large is entitled to access it, although such an argument explicitly denies the community's collective entitlement. Uncertainty regarding legal protection is largely due collective entitlement not being recognized by the IPR regime as, in most cases, the author or inventor of the TK cannot be precisely identified. Moreover, the knowledge itself is rarely documented for any protection to be sought (Gervais, 2005). This unknown authorship and undocumented knowledge pose challenges in accommodating TK within the existing IPR-type legal regime (Gervais, ibid). Because of this legal complexity, potential benefits arising from the use of TK also cannot be shared with its holders, despite the fact that TK can have significant commercial value particularly that used for medicinal purposes (Long, 2006).

While there is obvious agreement concerning the value and importance of TK, scholars, policymakers, and law makers have called for an effective legal regime for its protection. Since the late 1970s, WIPO has developed a potential model provision regarding a *sui generis* system for the protection of the expressions of folklore in collaboration with the United Nations Educational, Scientific and Cultural Organization (UNESCO). In 2000, WIPO established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC-GRTKF) to investigate the relationship between IPR, biodiversity, and traditional knowledge (WIPO, 2006). The IGC investigated whether it was possible to enable TK holders to acquire and use IPR where available for the short term. It also investigated longer-term possibilities to develop new standards to protect TK that was not protected by existing IPR tools, to elaborate on an international framework for TK protection, and to develop a system of "community" or "collective" rights to protect TK (Bhatti, 2000).

As the process continued within the IGC, a potential solution was suggested:

once the inventors are identified and the rights of such inventors are transferred to the community at large, the community can be granted patent or copyright rights without necessarily threatening the foundations of existing IPR mechanisms (Arewa, 2006). It is understood that these types of TK require different levels of protection requiring a more diverse mechanism than that of pure property protection (Long, 2006). However, such an approach involved fragmented national procedures for recognizing a community as a legal person, and therefore, it did not offer a uniform solution for general applicability. Moreover, the challenge concerning documentation made it complex; the lack of documentation of knowledge was regarded as a "double-edged sword" (Gervais, 2005). Ownership rights cannot be granted for undocumented knowledge, as doing so may create social unrest and legal uncertainty. As a result, no precise rules are found to assign ownership rights to a community at large for an object of knowledge that has not been identified by any coherent, uniform legal mechanism. Nor is there any legal development perceived to include TK within the present form of the IPR regime (Gervais, 2005).

Concerning a completely new form of legal regime – the *sui generis* regime – there have been arguments that framework to protect TK must be developed with adequate flexibility (Gervais, 2005). It should contain a strategy related to the documentation and dissemination of TK, conversion of TK into products and services, and commercialization of the products and services (Bhatti, 2000). According to WIPO, a new TK protection system "need not entail an entirely new or stand-alone system, but could also include adapted or extended *sui generis* elements of existing IPR framework" (WIPO, 2002). Although progress within WIPO for new *sui generis* rights for TK has been on-going for decades, there is no sign of consensus on how to mitigate the basic complicacies of identifying the knowledge or its proper documentation with ownership rights (Gervais, 2005). Scholars, such as Hossain and Ballardini, argued for a principle-based approach following procedural mechanisms in a given context at multiple layers of decision-making. Such an approach calls for the implementation of human rights norms both at international and national levels (Hossain and Ballardini, 2021).

Role of CBD, TRIPS and Cultural aspects of TK

A bridge between the cultural orientation of TK and the community rights that emerge from such an orientation provides a pragmatic approach when TK protection is sought using a human rights framework specifically in the context of moral rights. Given that the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement excludes TK from protection due to its nature as not "trade-related," human rights regimes well recognize TK as moral rights (Haugen, 2005; Downes, 2000). The two main international human rights instruments – the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR) – explicitly refer to the protection

of minority culture and the right to take part in cultural life, both as an individual and as a group "in community with other members" (Article 27, ICCPR; Article 15(1), ICESCR), which explicitly apply to Indigenous communities. The treaty monitoring bodies within the framework of these two instruments, such as the Human Rights Committee (HRC) and the Committee on Economic, Social and Cultural Rights, provide a clear reference to Indigenous peoples' intellectual creations and innovations as rights to be protected, for which states ratifying the treaties incur a legal duty. General Comment 23 (1994) on Article 27 of the ICCPR and General Comment 21 (2009) on Article 15(1) of the ICESCR are authoritative statements providing an explanation as to how to interpret the provisions accommodating intellectual creations of Indigenous peoples and their knowledge as part of a right to culture.

The body of human rights law pertaining to the projection of Indigenous TK interacts with the CBD. Such interaction can also be argued to provide a protection regime for TK as part of the enjoyment of community culture. Article 8(j) of the CBD and work performed by the Working Group on the article address Indigenous TK from a biodiversity point of view, linked to the human rights interpretation applicable to Indigenous communities. Often, knowledge and innovations held by Indigenous peoples, in the spirit of the CBD, are considered a new cluster of rights – bio-cultural rights. Although there is no set definition for a bio-cultural right, the obligations set forth in the CBD, in particular under Article 8(j), when interacting with established human rights norms applicable to Indigenous peoples, form such rights. Such interactions provide reasonable grounds for an effective implementation regime for the protection of TK rights. Therefore, state obligation sunder both the CBD regime and IPR regime (with development taking place in WIPO's draft articles on the protection of TK) provide the basis to explore the protection of TK as part of human rights law. However, the normative guidance offered by international human rights law must be supplemented by national implementation procedures. Hence, the human rights framework offers normative guidance for the legal protection of Indigenous TK, supplemented by specific national regulations.

Traditional Medical Knowledge and Its Preservation by Indigenous Communities in India

India is a land of enormous cultural diversity and has long historical traditions and traditionally developed knowledge. It is a veritable emporium of herbs. The inhabitants of India have known of the medicinal uses of plants for centuries. Every herb may potentially be of medicinal value. Common people are ignorant of plants and species having had medicinal value and yet have included them in the list of medicinal ingredients. In a sense, when traditional medical knowledge is discussed in the Indian context, the term "Indigenous medicine" can refer to Ayurveda and Siddha, which are Indian in origin and development (AYUSH, 2021a). Indian

traditional medicine is not meant for only medical treatment but also represents a healthy life. Ayurveda is practiced all over India and in neighboring countries like Sri Lanka, Nepal, Bangladesh, and Pakistan ((AYUSH, 2021a). The Siddha system of traditional medical knowledge is practiced mainly in Tamil-speaking areas of southern India. Apart from Ayurveda and Siddha, the Unani system of traditional medicine is practiced in most parts of the country. It was introduced in India by Arabian scholars and physicians around 1350 AD. Others, like naturopathy and Yoga, which have lately become separate systems, identity with Ayurveda in specific basic approaches and certain areas (Ravishankar and Shukla, 2017). Another popular medical tradition is Sowa-Rigpa, one of the oldest and well-documented living medical traditions in the world. "Sowa Rigpa" is derived from the Bhoti language and means "knowledge of healing." Sowa-Rigpa is a traditional Tibetan medicine system practiced in the Himalayan belt of India. It is popular in Sikkim, Arunachal Pradesh, Himachal Pradesh, West Bengal's Darjeeling, and Ladakh's Union Territory.

Based on the WHO's strategies for integrating traditional medicine with complementary medicines into the public healthcare system, the Government of India established the Department of Indian Systems of Medicine and Homeopathy in 1995. In 2003, the Department was named AYUSH (acronym of Ayurveda, Yoga, Unani, Siddha, and homeopathy medical systems). Subsequently, on November 9, 2014, the Ministry of Ayush was established with a vision to revive the insightful TK of Indian systems of medicine and to develop and promulgate the Ayush systems of healthcare through the public healthcare system (AYUSH, 2021b).

Where the Indigenous communities in India are concerned, the so-called "Scheduled Tribe" has its unique traditional medical knowledge. Over 700 tribal populations live throughout India, comprising 8.6% (104 million) of the population and possessing TK connected to biodiversity in the surrounding environment (Census of India, 2011). Sharma and others reported that Indian tribal communities and other ethnic groups use more than 8,000 plant species and 25,000 folk medicine-based formulas in their healthcare. Every tribe has its traditional system of medicine, and it is considered a rich heritage of the group (Sharma et al., 2016). In a review, Sharma and Kumar concluded that medicines used by tribal people have great potential for discovering new and undiscovered medicines to cure human diseases and promote human welfare (Sharma and Kumar, 2015).

A brief overview of traditional medical practices of the Indigenous communities in India

These traditional medical practices of the Indigenous communities are practically governed by the medicine man, often called "shaman." Indigenous people believe that the shaman can interact with the spirit as a navigator. They are involved in ritual performances and in knowledge and wisdom. For example, Shamanism is highly

prevalent among tribes in Arunachal Pradesh, a northeastern state. Every tribe in Arunachal Pradesh has its specific shaman for performing rites and sacrifices. The Tani people of northeast India believe that Shamanism is as old as the emergence of humankind. The Buddhist tribes of Arunachal Pradesh have Indigenous priests whose services are employed during special rituals despite having Buddhist religious priests or Lamas in their community. Other tribes, like Galo, Wancho, Nocte, and Tangsa in Arunachal Pradesh also have Indigenous priests to perform rituals during the healing process of the disease concern (Indian Culture, 2021; Dabi, 2017). The Tripuri tribes of northeast India possess rich knowledge of the use of medicinal plants. This knowledge helps not only the Tripuri ethnic group but also neighboring communities in keeping healthy lives (Debbarma et al., 2017). Like the Tripuri tribes, many tribes in northeast India have adapted herbs, animal body parts, and ritualistic practices to maintain health since time immemorial (Deb and Sharma, 2015). In the eastern part of India, Datta and others noted that tribals from the Coochbehar district of West Bengal often use various plants to treat common physical ailments such asinjuries and stomach and abdominal disorders (Datta et al., 2014). Similarly, the Bhunnij, Kol, and Birhor (*mankidia*) tribes of the Simlipal Biosphere reserve in Odisha use various medicinal plants and animals for medical purposes (Sahu et al., 2011).

P.O. Bodding, a Norwegian missionary, contributed a classic work on Santal tribal traditional medicines and diseases in eastern India (Bodding, 1925). He critically discussed traditional medicine for curing diseases (Ray, 2019). Indian Indigenous people use curative and palliative knowledge of certain herbs, animals, and minerals to treat common ailments. The ingredients used for traditional health care by Indigenous people are also termed ethnomedicine. Ethnomedicine is the outcome of bold experimentation through "trial and error" methods for hundreds of years (Vedavathy, 2003). Ethnomedicinal investigations among the Baiga tribe of central India showed a list of 68 wild plants used to cure skin diseases, diarrhea, jaundice, cough, wounds, piles, urinary troubles, asthma, tuberculosis, snakebite, gynecological problems, heart diseases, and as eye drops (Ahirwar, 2017). Similarly, Mitra described the rich ethnomedicinal practices and healthcare management by traditional practitioners, birth attendants, bonesetters, faith healers, and diviners among the Hill Korwa and Birhor tribes in Chhattisgarh state in central India (Mitra, 2010).

Singh and others showed that ethno medicinal practices are an essential alternative medicinal practice of the local people for the Jakholi Block in the Northwestern Himalaya, India (Singh et al., 2017). The study also indicated their deep ethno medicinal knowledge over 78 plant species to treat 14 different aliments. In southern India, an ethnobotanical survey was conducted among the Irula ethnic group of the southwestern Ghats Mountains, reflecting a widespread practice of traditional medicinal plants. The Irula use their knowledge to treat asthma, digestive

problems, paralysis, skin diseases, and diabetes (Revathi and Parimelazhagan, 2010). The Gujjar tribe from the Bangus Valley of Kashmir Himalaya also uses enormous varieties of plant species to cure cold and cough, dysentery, worm infestation, and wound infection. The *hakims* (local traditional healers) of the Gujjar community prescribe herbal medicine as concoction, powder, paste, or tea (Ishtiyak and Hussian, 2017). Tribal herbal medicine is also used in traditional recipes, like "sik," served as a nutritious diet to pregnant women among the tribal communities of Chhota Bhangal in the western Himalaya (Uniyal et al., 2006).

Traditional medicine or "the people's health culture" usually entails an oral tradition of healing techniques and properties of plants and animal substances passed from one generation of healers to the next. In most tribal societies, supernatural forces are believed to cause disease. Traditional healers are viewed as members of mankind, nature, and supernatural entities who protect their communities and provide spiritual security (Kumar et al., 2020). In many communities, neither Ayush nor the allopathic doctor is approached first. According to a household survey of all districts of rural Meghalaya state in northeastern India conducted by Albert and others nearly 45% of the tribal population uses traditional medicine instead of the Ayush system of medicine to cure both minor and major diseases (Albert et al., 2015). Hence, Indigenous community members and their shamans preserve traditional medical knowledge from generation to generation in India. Indigenous people consider them their first line in healing any disease.

Traditional Medicinal Knowledge in India from the Viewpoint of an IPR Legal Framework

Despite the development of the public healthcare system in India, people in rural and remote regions are largely reliant on traditional medicine due to its affordability and accessibility and due to the core hearted, age-old belief system of the community at large. Due to the lack of formal governmental documentation of traditional medical knowledge and its oral transmission, the protection of traditional medical knowledge under the current IPR regime may have imposed specific questions on the extent of preserving traditional medical knowledge. India lacks a substantive regulatory tool to protect traditional medical knowledge, primarily due to the complexity of identifying the owner, as is the case more generally in protecting TK. Who owns specific traditional medical knowledge? Does it involve the rights of an individual, or a family, or a community, or traditional healers?

Acts like Drug & Cosmetics Act 1940 (amended 2009), Copyright Act 1957, Patent Act 1970 (Amended 2005), Geographical Indications of Goods (Registration and Protection) Act, 1999, and Protection of Plant Varieties and Farmer's Rights Act, 2001 exist. Still, not a single Act is exclusively formulated for protecting traditional medical knowledge under the IPR regime in India (Riya, 2020). Therefore, like the general complexity of the TK discussed earlier, the protection of traditional

medicinal knowledge in India suffers the same problems because the knowledge is un-codified and non-inventory in nature and passed orally from generation to generation. Sarkar and Singh indentified similar problem related to TK during their critical analysis on protection of Traditional Knowledge Bill, 2022 (Sarkar and Singh, 2022). Therefore, the legal incorporation of traditional medical knowledge especially that of Indian Indigenous people, has yet to be resolved. According to the WHO's Report on traditional and complementary medicine in 2019, India's Ayurveda, Unani, and Siddha pharmacopoeia are regulated under Drug & Cosmetics Act 1940 (amended 2009). However, there are also many monographs on single herbs and formularies of Indian herbal pharmacopoeia, including the traditional medicine of Indigenous people (like the monograph of Bodding), which are not considered under Drug & Cosmetics Act 1940 (WHO, 2019).

Role of Convention of Biological Diversity, Traditional Medicinal Knowledge and IPR in India

Concerning the traditional medicinal knowledge in the purview of the IPR framework in India, specifically when held by Indigenous people, it is impossible to overrule three biodiversity-related instruments, i.e., the CBD adopted at the Rio Conference in Brazil in 1992, the Biodiversity Act of India of 2002, and, subsequently, the legal provisions under Indian Patent Amendment Act, 2005 (IPAA). The importance of the 1992 convention lies in formulating policies to protect and promote the sustainable use of biological resources and the equitable benefits arising from TK. In India, traditional medical knowledge and practices are essential resources for the survival of the Indigenous population. India, one of the signatories of the CBD, is obligated to pay due attention to the benefit-sharing of marketable and inherited property resources held by Indigenous peoples. At the very least, procedures for gaining the prior and informed consent of Indigenous communities must be established to recognize the knowledge; this was an essential milestone.

The Indian Parliament passed the National Biodiversity Act in 2002 to fulfill the obligations under the CBD at the national level. With the Act's implementation, two significant institutions have been established, i.e., the National Biodiversity Authority (in Chennai), and a State Biodiversity Board for all Indian states, incorporating local bodies like *panchayats*, municipalities, and corporations. One of the responsibilities of this institution is to make reasonable efforts to prevent the issuing of IPR in other countries based on the exploitation of biological resources or associated TK. According to the Act (Section 6), the National Biodiversity Authority (NBA) can permit both Indian citizens and foreign nationals to research biological resources in India. The NBA also has the authority to approve claiming patents of Indian biological resources. However, there was a lack of thoughtful provisions regarding the protection of Indigenous medical knowledge in the National Biodiversity Act (Singh, 2021). Section 3 of the IPAA has three significant

provisions regarding the prohibition against obtaining a patent for invention and associated traditional knowledge. According to Section 3(e), first, herbal and medicinal plants of India are known and used for various therapeutic and cosmetic purposes. Any new product or process of their making should not be patentable. Second, *Vaids* and *Hakims* use various devices for the extraction, purification, and preparation of traditional Ayurvedic medicine, which should not be part of patentable inventions as per Section 3(f). Third, traditional treatment methods are (thus) non-patentable; these include a considerable number of plant and animal genetic resources according to Section 3(i) (Chakrabarti, 2019).

Traditional Knowledge Digital Library (TKDL): Limitation and success

To preserve and protect traditional medical knowledge in India, the Government of India initiated a project, namely the TKDL, in 2011. The TKDL has a unique proprietary database with 34 million entries. It integrates various knowledge systems—Ayurveda, Unani, Siddha, and modern science and medicine. Ayurveda can be classified into four divisions per usage, i.e., pharmaceutical preparation (*Kalpana*), personal hygiene preparation, preparation through food or foodstuff, and beverages and preparation of biocidal fumigatives (*Dhupana, Krimighna*). Pharmaceutical preparation is also sub-divided into several groups per the nature of the product whether based on plants (*Audbhida*), based on animals (*Jangama*), based on minerals (*Parthiva*), and characterized by diseases (*Roga*), characterized by action (*Karma*), and per mode of administration and other miscellaneous types. The TKDL is available to all patent offices that have signed a non-disclosure access agreement with it. Under this agreement, patent examiners may only use the TKDL database for search and examination purposes. TKDL content can only be disclosed to third parties for citation purposes. The TKDL Access Agreement has integrated non-disclosure mechanisms to protect India's interests and counter any possible misuse. India has signed TKDL Access Agreements with the European Patent Office (EPO) and patent offices in Australia, Germany, Japan, Canada, New Zealand, the United States, and the United Kingdom (Ansari, 2020; Chakravarty and Mahajan, 2010; Twarog and Kapoor, 2004). Fredriksson argued that although the formulation of the TKDL helped revise the International Patent Classification to better incorporate traditional medicinal knowledge, TK can be de-contextualized to express owners' legal rights (Fredriksson, 2023). Despite this initiative, the TK of Indian people, specifically Indigenous people, is at risk of bio-piracy.

A classic example of bio-piracy in connection to Indian TK is the patent on turmeric (*Curcuma Longa Linn.)*. Indians have used turmeric for centuries for therapeutic uses. They have always used the rhizomes of turmeric in cooking. In 1995, two University of Mississippi Medical Center scientists received a patent from a U.S. agency on the use of turmeric for healing. Later, the Indian Council of Industrial Research (CSIR), New Delhi, challenged this patent by giving supporting

documents on the use of turmeric in wound and rash treatment, for thousands of years, as traditional medical knowledge of India. After judging the case, the U.S. patent office revoked the patent (in 1997) due to a lack of novelty and innovation; the therapeutic usage of turmeric is recorded in ancient Ayurvedic writings.

A similar situation was observed in the case of the neem patent. In 1994, the global firm W.R. Grace and the U.S. Department of Agriculture obtained a patent on the antifungal properties of neem from the EPO. Later, Indian scientists protested this decision and claimed that hydrophobic extracts from neem seeds were known and employed to treat skin disorders and fungal infections. The EPO decided to cancel the patent (CSIR & AYUSH, 2021). Another example of bio-piracy of Indigenous people's medical knowledge was observed among the Yanadis tribal community in southern India. A case study made evident that more than 200 plant species have been used in modern medicine without acknowledging and rewarding the Yanadis population. Yanadis healers felt that the government should give formal recognition and rights over their TK to sustain their medicinal knowledge and practices (Vedavathy, 2009). Javed and his team recently proposed regarding the "fiduciary rights" of traditional health knowledge holders in the Indian public health system through their writing (Javed et al., 2020).

The Government of India approved the National Intellectual Property Rights policy on May 12, 2016, and has formulated a committee for the monitoring of IPR-related issues throughout India. The central vision of the current IPR policy is to bring all IPR-related statutes and agencies under a single umbrella and to find commonalities and differences between previous IP policies and Acts. The main aim is to enhance public awareness of preserving and using TK. Unfortunately, traditional medical knowledge has not been separated from TK. The policy stretches upon the preservation of TK through the TKDL but does not explain issues of protection of Indigenous peoples' (Indian tribes) traditional medical knowledge and its conservation (Government of India, 2016).

Challenges in Preserving Traditional Medical Knowledge in India

Challenges in preserving TK, specifically traditional medical knowledge in Indian Indigenous communities, are complex and multidimensional. As discussed earlier, existing statutes and patent laws are inadequate to protect traditional medical knowledge and biodiversity (Ansari and Chaubey, 2020). Identifying the authentic owner of traditional medical knowledge is the primary challenge. Similarly, identifying the efficacy of traditional medicinal materials is another hindrance to promoting traditional medical knowledge in the purview of modern medical understandings. Traditional healers often do not know the side effects of traditional medicine, which creates a dilemma for the applicability of traditional medicine beyond a specific community. In addition, lack of governmental supervision over the exploitation of traditional medicinal herbs by pharmaceutical companies has

adversely affected the existence of medicinal plants in their wild habitats. Moreover, the production and selling of herbal medicine in India often violates international market norms (Shi et al., 2021).

IPR mechanisms, in India as well as globally, do not cover non-systematic, un-scientific, undocumented knowledge, whereas customary law is not applicable outside the community. The changing lifestyle of modern Indian Indigenous communities may create another constraint to documenting TK. The growing attitudes of tribal youth toward using ancient traditional medical knowledge are the major degenerative factor. In addition, the assimilation of the comparatively small Indigenous groups into (larger) neighboring non-Indigenous/Indigenous communities has forced these groups to dilute precious traditional medical knowledge. Negi and Azeez found that age-old traditions of Indigenous medical knowledge among Indian Indigenous communities are rapidly diminishing (Negi and Azeez, 2022). The day-to-day life of Indigenous people is filled with dilemmas in choosing appropriate healthcare services. In brief, the traditional medicinal knowledge of Indigenous people is vanishing because of various socio-economic, environmental, and political factors. Rural/remote habitation and low socio-economic status result in the non-availability, inaccessibility, and lack of affordability of modern public healthcare facilities.

Chakrabarty reported a case study of the Shabar tribal group in eastern India regarding diminishing traditional medical knowledge and practices due to unplanned forest rehabilitation (Chakrabarty, 2019). Guruprasad and others described the loss of excellent traditional medicinal knowledge among the Iruliga tribal community in the Western Ghats; Iruliga youth denied practicing traditional medicinal knowledge due to their adoption in urban-centric life (Guruprasad et al., 2013). Panghal and others depicted vanishing traditional medical knowledge among the Saperas community (snake charmers) of northwest India (Panghal et al., 2010). Despite the vast plant medicinal knowledge among the Saperas, the banning of snake charming by the Indian government (for wildlife conservation) may be forcing them to adapt to different socio-economic environments. As a result, the distance between nature and the Saperas has increased as reflected in the rapid disappearance of traditional medicinal knowledge. Finally, 'modern' science may deem TK inferior, and commercial exploitation by 'others'(e.g., bio-prospecting, the use of Indigenous designs) may also pose significant challenges in preserving the traditional medical knowledge of Indigenous people.

Conclusion and Recommendation

General challenges face the protection of Indigenous TK while underlining the importance of Indigenous medicinal knowledge. While "one size fits all" solutions to such challenges may be inappropriate, India has shown progress with its unique approach. The creation of the TKDL in 2011 was a remarkable achievement and

was crucial for the protection of medicinal knowledge. Yet, the traditional medical knowledge of Indigenous people is rapidly disappearing due not only to the adoption of modern ways of living among Indigenous groups but also to lack of governmental policies on the preservation and protection of traditional medical knowledge and its general IPR-type framework. There are enormous inconsistencies in the rationale of temporal policy formulation for revitalizing local health traditions, as was suggested by Mishra and others (Mishra et al., 2018). Further, it is not culture alone but a lack of opinions that govern final medical care-seeking decisions. Traditional medical systems, modern medicine, and public health coexist in India. We need to integrate the different segments between traditional ethno-medicine and the primary healthcare system. The government should develop a standard inventory of the traditional medicine of Indian Indigenous people. While availability of such inventory would identify specific traditional knowledge for seeking a protection regime, it is also important to note that there is heterogeneity in the practice of traditional knowledge. Not all sorts of traditional (medicinal) knowledge practiced by communities can be available in inventories, hence the complexity exists to find a homogenous legal regime for the protection of the knowledge. Therefore, a human rights approach, particularly from the viewpoint of cultural rights, could be a best fit both to recognize the traditional knowledge as a cultural right and to offer the community as the right holder of the knowledge. Hence, appropriate guidelines to that direction should be formulated for incorporating the dispersed traditional medical knowledge of Indigenous people under a coherent framework so that they can enjoy, and utilize, their rights to this knowledge. Indigenous traditions in India and throughout the world, and lessons learned from these traditions, can be compared and further scrutinized to develop a sophisticated understanding of the importance, and protection, of Indigenous traditional medicinal knowledge, both in and beyond India.

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